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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/363,748	07/30/1999	CAROL WATKINS	108137.701	8501

27160 7590 04/10/2002

PATENT ADMINSTRATOR  
KATTEN MUCHIN ZAVIS  
SUITE 1600  
525 WEST MONROE STREET  
CHICAGO, IL 60661

EXAMINER

CRANE, LAWRENCE E

ART UNIT

PAPER NUMBER

1623

DATE MAILED: 04/10/2002

Please find below and/or attached an Office communication concerning this application or proceeding.



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<b>Office Action Summary</b>	Application No. <b>09/363,748</b>	Applicant(s) <b>Watkins et al.</b>	
	Examiner <b>L. E. Crane</b>	Group Art Unit <b>1623</b>	

**- THE MAILING DATE of this communication appears on the cover sheet beneath the correspondence address -**

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE **--3--** MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be filed after six months from the date of this communication.
- If the prior for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 USC §133).

## Status

- ☒ Responsive to communication(s) filed on **-11/20/01 (CPA Request)-**.
- ☐ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- ☒ Claims **--39-50--** are pending in the application. Claims **-1-38-** have been cancelled.
- Of the above claim **--47--** is withdrawn from consideration.
- ☐ Claim(s) **--1--** is/are allowed.
- ☒ Claims **--39-46 and 48-50--** are rejected.
- ☐ Claim(s) **--1--** is/are objected to.
- ☐ Claim(s) **--1--** are subject to restriction or election requirement.

## Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on **-1-** is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on **-1-** is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119(a)-(d)

- ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119 (a)-(d).
- ☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been received.
- ☐ received in Application No. (Series Code/Serial Number) **-1-**.
- ☐ received in the national stage application from the International Bureau (PCT Rule 17.2(a)).
- \* Certified copies not received: **-1-**.

## Attachment(s)

- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). **--1--**
- ☐ Notice of Reference(s) Cited, PTO-892
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Interview Summary, PTO-413
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Other: **-1-**

U.S. Patent Trademark Office

## Office Action Summary

PTO-326 (Rev. 06/19/01)

S. N. 09/363,748

Part of Paper No. **20**

Copy for **FILE** ☐ APPLICANT

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Applicant's submission of a "Continued Prosecution Application Request," and "Change of Correspondence Request/Associate Power of Attorney" were received November 20, 2001 and made of record. As no amendments or arguments have been received the remainder of this Office action represents a recapitulation of the previous Office action and has been made non-final to permit applicant the opportunity to respond with amendments to the previous grounds of rejection.

Claims 1-38 have been cancelled and new claims 39-50 have been added as per the amendment filed January 12, 2001. A supplemental Information Disclosure Statement (IDS) also filed January 12, 2001 has been received and made of record as of the date of the instant Office action.

Claims 39-50 remain in the case.

Newly submitted claim 47 is directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: the "other" compounds listed in the noted claim are not all found in the cancelled claims 30-31 or in any other claims now cancelled.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly claim 47 has been withdrawn from consideration as being directed to a non-elected invention. See 37 C.F.R. §1.142(b) and MPEP §821.03.

Claims 39-46 and 48-50 are rejected under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the

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specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

5 Inspection of the instant disclosure reveals no specific test data to support the generic limitations ("a neurological disorder," "a memory disorder," "memory disorder associated with aging") directed to the treatment of a disease condition or conditions, by the administration of uridine, cytidine, mixtures of uridine and cytidine, or any other uridine- or cytidine-containing binary or higher order mixtures of active or  
10 prodrug/precursor ingredients. For example, the noted claims read on the treatment of senile dementia, HIV-related dementia, and Alzheimer's disease, but the instant disclosure fails to provide any evidence that the instant method is effective in the treatment of any one of these disease conditions. Therefore, the instant disclosed exemplifications relevant to  
15 the instant claims are deemed to be entirely prospective and therefore lacking any enabling effect.

Applicant's arguments filed January 12, 2001 have been fully considered but they are not persuasive.

20 The instant amendment has not effectively addressed the original failure of the instant disclosure to provide an enabling disclosure. Applicant's argument alleges that the instant grounds of rejection is no longer applicable " ... because the new claims relate to a method of increasing cytidine in the brain by administration of uridine." Examiner respectfully disagrees, noting that the subject matter of new claim 39 is  
25 nearly identical in scope with the subject matter of original claim 1. Applicant is reminded that it is well known and established that "law requires that disclosure in an application shall inform those skilled in the art how to use appellant's alleged discovery, not how to find out how

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to use it for themselves." *In re Gardner et al.*, 166 USPQ 138 (CCPA 1970). Therefore, the instant grounds of rejection has been slightly amended in light of the newly submitted claims, but remains effectively the same and has been maintained for the reason noted.

5        Claims 39-46 and 48-50 are rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

10        Claim 39 appears to be an incomplete method of treating claim because it fails to include a specific disease condition to be treated. This means that the limitations added in claims 41, 42 and 45 lack proper antecedent basis in claim 39, and/or that claims 41, 42 and 45 are entirely superfluous because they fail to further limit any patentable feature of independent claim 39.

15        Applicant's arguments with respect to claims 1-38 have been considered but are moot in view of the new grounds of rejection.

20        In claim 39, the term "uridine or a precursor thereof" is directed to subject matter (or a precursor thereof) which as a functional term directed to chemical species lacks adequately defined metes and bounds. The same problem reoccurs in claim 50, and a similar problem ("uridine or its precursor") occurs in claims 40 and 43-44.

Applicant's arguments with respect to claims 1-38 have been considered but are moot in view of the new grounds of rejection.

25        In claim 41 the term "a neurological disorder" is indefinite for failure to particularly point out the specific disease condition to be treated.

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Applicant's arguments with respect to claims 1-38 have been considered but are moot in view of the new grounds of rejection.

5 A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, dependent claim 41 recites the broad recitation "neurological disorder," and independent claim 39 recites "brain cytidine levels" which is a narrower statement of the range/limitation of the area of effect of the treatment being claimed.

Applicant's arguments with respect to claims 1-38 have been considered but are moot in view of the new grounds of rejection.

25 In claims 42 and 50 the term "a memory disorder" is indefinite for failure to particularly point out the specific disease condition to be treated. A similar problem occurs in claim 45 ("memory disorder associated with aging").

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Applicant's arguments with respect to claims 1-38 have been considered but are moot in view of the new grounds of rejection.

5 In claim 46 the term "a second compound" is indefinite for failure to define which compounds are included as ingredients and which compounds are not. The instant term does not exclude any other chemical compound, including obviously inappropriate embodiments such as arsenic oxide and strychnine.

Applicant's arguments with respect to claims 1-38 have been considered but are moot in view of the new grounds of rejection.

10 Claim 48 lists exemplifications of the "second compound" but then inappropriately expands the subject matter beyond the scope of claim 46 by including the term "or mixtures thereof." Therefore, claim 48 is lacking proper antecedent basis in claim 46, which is limited to a single "second compound" only. A very similar problem occurs in claim 49  
15 ("or combinations thereof").

Applicant's arguments with respect to claims 1-38 have been considered but are moot in view of the new grounds of rejection.

20 Claim 49 the terms "a uridine phosphorylase inhibitor," "[a] uridine secretion inhibiting compound," and "[a] uridine renal transport competitor" are indefinite functional terms because they refer to a single compound but fails to define which specific compounds are included and which compounds are not included within the metes and bounds of the instant claims.

25 Applicant's arguments with respect to claims 1-38 have been considered but are moot in view of the new grounds of rejection.



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The following is a quotation of the appropriate paragraphs of 35 U.S.C. §102 that form the basis for the rejections under this section made in this Office action:

"A person shall be entitled to a patent unless -

- 5 (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent."
- 10 (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States."
- 15 (c) the invention was described in a patent granted on an application to another filed in the United States before the invention thereof by applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent."

Claims 39-46 and 48-50 are rejected under 35 U.S.C. §102(b) or (e) as being anticipated by any one of PTO-892 references B, L, R, S, T, U, V, W, X, Y and Z.

20 Applicant is referred to each of the noted references wherein various uridine and uridine/cytidine mixtures and/or prodrug mixtures are used to treat various neurological disease conditions including those of cerebral/brain origin including deterioration of memory.

Applicant's arguments filed January 12, 2001 have been fully considered but they are not persuasive.

25 Applicant states that the submission "... of new claims renders the rejection moot." Then applicant proceeds to argue the inapplicability of each of the cited references in light of the original claims. In the case of reference B applicant argues that this reference "is directed to the use of

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uridine as a growth promoter and a treatment of pathological aging and neuronal degeneration." (emphasis added) This argument is inconsistent with applicant's reliance in claim 41 on the overlapping term "neuronal disorder." In light of what appear to be conclusory summaries of this and the remaining references wherein no specific reference is made to which particular portion(s) of each reference provides a proper basis for the stated conclusion, examiner concludes that applicant's arguments are not sufficiently detailed to be either convincing or entirely understandable.

10 Papers related to this application may be submitted to Group 1600 via facsimile transmission(FAX). The transmission of such papers must conform with the notice published in the Official Gazette (1096 OG 30, November 15, 1989). The telephone numbers for the FAX machines operated by Group 1600 are (703) 308-4556 and 703-305-3592.

15 Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner L. E. Crane whose telephone number is 703-308-4639. The examiner can normally be reached between 9:30 AM and 5:00 PM, Monday through Friday.

20 If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Gary Geist, can be reached at (703)-308-1701.

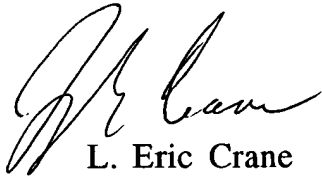
25 Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is 703-308-1235.

Serial No. 09/363,748

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LECrane:lec  
11/28/01



L. Eric Crane  
Patent Examiner  
Group 1600